Via E-mail

May 27, 2011

Dr. Angela Nugent
Designated Federal Officer (DFO)
EPA Science Advisory Board (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW.
Washington, DC 20460

Re: EPA Science Advisory Board Staff Invitation to a Session on Public Involvement in EPA Advisory Activities Supported by the SAB Staff Office; 76 Fed Reg. 27315

Dear Dr. Nugent:

We, the undersigned organizations, wish to inform you that we will participate in the June 1, 2011 session on public involvement in activities related to the Science Advisory Board (SAB). Our major concerns, as indicated in the attached written comments, include the nomination of experts for committees and panels, public involvement in meeting and report development, and the general operating procedures of the SAB and its peer review role and process. We request time at the public session for a representative to make a short oral statement discussing our comments.

If you need to contact our group please call Mr. Eric Dubé of Steptoe and Johnson LLP, who can be reached at 202-862-5765.

Thank you in advance for your consideration in this matter. We look forward to actively participating in the June 1 meeting.

Sincerely,

Industrial Minerals Association - North America
Mulch & Soil Council
National Mining Association
National Stone, Sand, and Gravel Association
North American Metals Council
Organic Arsenical Products Task Force
Responsible Industry for a Sound Environment
Treated Wood Council
USA Rice Federation
Western Business Roundtable
Wood Preservative Science Council

Attachments

Attachment 1

Testimony of [Name] before the EPA Science Advisory Board Session on Public Involvement in EPA Advisory Activities Supported by the SAB Staff Office

June 1, 2011

I am [name], here as a member of an *ad hoc* coalition of interested parties that have closely followed the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) assessment of inorganic arsenic.

I would like to thank the SAB Staff Office for this opportunity to comment on public involvement related to EPA peer-review committees, especially the Science Advisory Board (SAB). Given the ever increasing importance of the role of science in EPA decision-making, along with EPA's reliance on peer-review panels such as the SAB as part of EPA's decision-making, the SAB review process has over the years evolved to become a pivotal forum for many major EPA decisions and initiatives.

At the same time, increasingly, the EPA peer-review process has come under suspicion of inherent bias and even manipulation by EPA procedures and staff. Some observers view the SAB process as subject to varying degrees of manipulation, even if unintended, simply by the way the committee operates in its selection of panel members and in such key operating procedures as the determination of charge questions, agenda setting, or even in the scheduling and time-management of meetings. These issues have surfaced most frequently at the work group level.

Unfortunately, many of these concerns about SAB risk assessment peer review have been exhibited throughout the history of EPA's risk assessment of inorganic arsenic. Over a period of many years, EPA has sought SAB review of its arsenic assessment, and parties closely following this effort

have identified serious shortcomings in the process that ultimately reflect badly on EPA's stated goals of transparency and sound science as the foundation for its risk assessment procedures and reports.

In our view, the most recent SAB review activity in this area, which centered on a May 2010 draft report by the Inorganic Arsenic Cancer Review Work Group, was marked by a variety of actions and omissions that illustrate some of the problems with EPA's current peer-review process. Among these shortcomings are the following:

1. An unrealistically short time period was allowed for the public and Work Group to complete its review of and comment on the draft report.

2. Instead of asking the panel for a review of all the critical scientific assumptions, inputs, and methodologies that underlay the report and its conclusions, EPA staff very narrowly crafted the charge questions. This approach avoided review of some key questions, including potentially contentious issues that had not been peer reviewed since 2001. Contrary to the basics of good science, it also foreclosed the review of relevant newer data, thereby skewing the outcome on certain of these key issues.

3. The Work Group panelists were chosen by the SAB, and, in contrast to the National Academy of Sciences (NAS) approach, there was no public opportunity to examine the candidates or suggest alternative panelists with relevant backgrounds. It goes without saying that the composition of a scientific review panel can profoundly affect the outcome of the review process. Selecting the panel members entirely as an in-house process undercuts the credibility and

utility of that process. In addition, EPA inexplicably excluded all panelists from an earlier (2007) SAB panel from the newest review.

4. Witnesses were allowed only five minutes before the Work Group panel – which is insufficient time for any meaningful dialogue between the panelists and the witnesses.

5. The 2010 Work Group did not review, approve, or revise the EPA charge although this has been standard practice in peer review at the NAS and in some past SAB meetings. Blindly going forward without giving any independent thought to the basic road map for an important review is a lapse with troubling implications.

6. Although five members of the 2005 SAB panel, which had produced a valuable report in 2007, were highly critical of certain aspects of the draft 2010 Review, their concerns were overlooked by the most recent panel.

7. There was no apparent attempt by EPA or the Work Group to address the serious and fundamental objections raised by the scientific testimony at the meeting.

8. EPA's goal of transparency was plainly undercut by the absence of a transcript of the meeting, which would reflect the discussion better than a carefully worded after-the-fact summary.

9. Several remarks by panel members at the meeting were made more dilute in the written final report, including explicit comments about the narrowness of the

charge questions. The lack of a meeting transcript meant that this discrepancy was apparent only to those in attendance.

Unfortunately, the case example of the inorganic arsenic assessment exhibits many of the problems cited by critics of the SAB's peer review of EPA's science assessment procedures and products. Commonly identified issues include:

- Panel members are selected by a less than transparent process with unclear criteria for selection and no opportunity for the interested public to raise concerns, and consultants for, and employees of, industry are routinely excluded -- unlike the disclosure process used in NAS panels, which includes a full range of interested scientists to ensure expertise and balance;

- Charge questions are written by EPA program staff with seemingly little review by the SAB staff and often are perceived, with good reason, as intentionally narrowing the focus of review to help drive it towards a pre-determined set of conclusions;

- Often there are severe and unrealistic limitations on the time allotted for public comment or presentations to the panel, which can inhibit or hinder the full airing of relevant additional scientific information;

- Relevant materials (supporting documentation, draft assessments, public comments) are sometimes provided to the public only a short time before SAB meetings, making it difficult for interested members of the public to review and assess those materials;

- Interaction between the panel members and presenters is often discouraged by the rules of participation;

- No rigorous effort is made to ensure that prior SAB or peer review recommendations have been addressed and appropriate changes made or reasons articulated why those recommendations have been rejected; and

- Important questions raised by the presenters or the public can be summarily ignored by the panel as a result of the framework underpinning the meeting (*e.g.*, a narrowly written charge enables and even encourages the panel to overlook highly relevant questions that fall outside its declared scope).

Regardless of whether one agrees or disagrees with the outcome of any particular EPA review process, the basic and pervasive shortcomings that afflict the current SAB review process undermine the validity and legitimacy of EPA's scientific conclusions

Beyond these significant process and procedural flaws is the core failure of the SAB review process itself to identify key lapses and other weaknesses in EPA's science reviews as part of IRIS. As a result, the SAB review process often fails to support the mission of the program office requesting the review in the first place.

In sum, the inorganic arsenic assessment is but one example of how the mission of the various EPA program offices that requested the IRIS update is not fulfilled, enhanced, or otherwise facilitated by EPA's current processes (either the IRIS risk review process or the SAB's independent review of the IRIS assessments). An inconvenient fact of regulatory life consistently ignored by the SAB

review process is that the end product of an IRIS assessment is often devoid of practical utility for risk management purposes. Only if the process is repaired can the risk management conclusions contained in an IRIS assessment truly serve the needs of the EPA program offices responsible for acting on those conclusions.

Thank you for the opportunity to provide these comments.

Attachment 2

Comments for the EPA Science Advisory Board Session on Public Involvement in EPA Advisory Activities Supported by the SAB Staff

June 1, 2011

The National Academy of Sciences committee (the Committee) that reviewed EPA's draft hazard assessment of formaldehyde for the Integrated Risk Information System (IRIS) identified both specific and general limitations in the assessment, that it concluded needed to be addressed by EPA through revision (NRC, 2011)[1]. The Committee also noted recurring problems with EPA's IRIS assessments for chemicals beyond formaldehyde and in chapter 7 of its April 2011 report it provided guidance on what it considers critical elements for the development of a scientifically sound IRIS assessment. The Committee noted that many of the elements in its guidance are basic and have been addressed in numerous EPA guidelines; however, implementation by the Agency does not appear to be systematic or uniform in its development of IRIS assessments.

Several of the Committee's guidelines for EPA hazard assessments are applicable to the Agency's draft 2010 cancer hazard assessment of inorganic arsenic for IRIS (EPA, 2010)[2]. For example, on page 122 in the NAS report the Committee stated it is important that EPA assessments use standardized review and evaluation approaches when reviewing various types of studies to ensure uniformity.

In a March 25, 2010 letter to EPA from five members of the 2007 Science Advisory Board (SAB) Arsenic Review Panel, the members noted that while the Agency reviewed a number of recent, more robust epidemiology studies on inorganic arsenic in drinking water it failed to use the "uniform performance criteria" recommended in the Panel's 2007 report for reviewing the studies. By way of example, the members indicated that EPA inconsistently cited smoking behavior in the epidemiology studies "even though a large body of epidemiological literature has documented smoking behavior as a co-carcinogenic or synergistic factor in bladder and lung cancer causation." The members also noted other key factors that were not consistently evaluated by EPA in its literature review, including the degree of exposure misclassification, study response / participation rates, reliance on imputed exposure levels, estimates of exposure variability, control selection methods in case-control studies, number of persons at various arsenic drinking water concentration categories, and the influence of these factors on the magnitude and statistical stability of risk estimates.

In another example where the draft arsenic assessment falls short, the NAS Committee, in its guidelines for weight-of-evidence evaluation of a chemical's hazard, indicated that assessments should "unify consideration of outcomes around common modes of action rather than considering multiple outcomes separately." (p. 122). Again in their letter, the five SAB members noted that in EPA's summary of its review of *in vitro* mode of action studies, "no coherent critical integration and evaluation of these data is presented to address potential discrimination of key events in inorganic arsenic's carcinogenic mode of action. Meanwhile, other scientists have successfully evaluated, integrated and published critical reviews of this data base."

These are just two examples of where EPA's current draft assessment of inorganic arsenic does not meet the NAS' criteria for a scientifically sound IRIS assessment. These and other limitations noted in public comments by experts in the field of arsenic toxicology suggest EPA did not conduct a thorough or proper review of the scientific evidence on inorganic arsenic's carcinogenic potential, thereby raising substantial uncertainty regarding EPA's conclusions in its draft assessment.

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[1] National Research Council (NRC). 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde, Prepublication Copy". April.

[2] U.S. Environmental Protection Agency (EPA). 2010. "Toxicological Review of Inorganic Arsenic, In Support of Summary Information on the Integrated Risk Information System (IRIS)". Final Draft, February.